16715/CPA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of: William J. Rea, MD, et al. Attorney Docket: 16715/CPA2

Serial No.: 08/902,692 Art Group Unit: 1644

Filed: July 30, 1997 Examiner: Schwardon, R., Ph.D.

For: **AUTOGENOUS LYMPHATIC FACTOR FOR MODIFICATION OF T AND B LYMPHOCYTE PARAMETERS**

RESPONSE TO OFFICE ACTION

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

This is a response to the Office Action dated September 29, 2000.

The Examiner's continued attention to the application is appreciated. Both sides have gone round and round over certain issues. Both sides seem annoyed and frustrated.

As suggested by the Examiner, several months ago the Applicants asked an expert in the field to review the application for the purpose of submitting additional evidence in the record as to how a person of skill in the art would interpret some of the language used in the specification. Unfortunately, the expert has been suffering from severe back pain and recently had major back surgery. After the expert recovers sufficiently to continue working on the matter, Applicants plan to submit such evidence.

Meanwhile, the Applicants request the Examiner to take a step back and, if possible, reconsider the impasse. This might save both sides a lot of time and trouble.

Claims 49-66 were rejected under 35 U.S.C. § 112, first paragraph. Claims 65 and 66 were also rejected under 35 U.S.C. § 112, second paragraph.

The steps 1-15 of the preferred procedure according to the invention for making "ALF" are described at pages 9-10 of the specification. Both sides appear to agree that this detailed and complete procedure is clear to persons skilled in the art.

Furthermore, general statements in an application regarding an invention should be construed to cover the preferred procedure. For example, the general statement that "The preferred embodiment of the method for preparing the invention involves collecting blood from the ill individual and growing the normal lymphocytes in culture, harvesting the propagated cells, and collecting the biological regulator (ALF) from the cells for use in clinical treatments" at the

bottom of page 8 of the specification is specifically directed to the following steps 1-15 of the preferred procedure according to the invention. As a starting point, any interpretation of the general steps, including the step of "growing the normal lymphocytes in culture" should be made consistent with the specific steps 1-15 of the preferred procedure.

The Examiner's prior interpretation of this general language would seem to require something more or different than what is described in steps 1-15 of the preferred procedure. In particular, a claim reciting the use of "normal" lymphocytes would arguably require some additional separation step, which is not described in steps 1-15 of the preferred procedure described at pages 9-10 of the specification. Applicants do not understand, for example, what part of Claim 49, steps (a)-(e) is not supported or described by steps 1-15 of the preferred procedure described at pages 9-10 of the specification.

A premise of the invention is that even an ill person will have some normal lymphocytes included in the one or more isolated "lymphocytic layers" obtained from the person's blood sample. For example, the originally-filed specification at page 6, line 9-10, discloses "preparing ALF from the patient's own normal (non-cancerous or otherwise dysfunctional) lymphocytes." The specification also discusses normal and abnormal functioning lymphocytic cells by reference to the lymphocytic cell cycle. This is a measure based on a number of cells in the aggregate, not the appearance of a single cell.

The Examiner also rejected Claim 65, which was presented to help clarify this premise of the invention by including the step of "isolating mixed T and B lymphocytes from the blood sample, which includes at least some normal T and B lymphocytes." But this was rejected as being new matter, despite the statements in the originally-filed application about the normal "preparing ALF from the patient's own normal (non-cancerous or otherwise dysfunctional) lymphocytes" and despite the steps 1-15 of the preferred procedure according to the invention. Applicants do not believe this is a fair or proper interpretation of their application.

Claims 49-66 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over Youdim et al. in view of Warren. Neither Youdim nor Warren teach or suggest propagation of the cells. By any meaningful definition, one cannot propagate lymphocytes by "incubation" at 37 degrees for 20 minutes and without any culture medium. As would be appreciated by a person of skill in the art, Warren is actually disclosing a separation step, not a cell propagation step. By any meaningful definition or standard whatsoever, Warren does not teach or suggest any propagation of lymphocytic cells.

Reconsideration and allowance of pending Claims 49-66 is respectfully requested. If a telephone call would help the prosecution of the application, the undersigned can normally be reached at the number below.

DATED: March 29, 2001

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